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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,987	10/23/2003	Steven M. Griffiths	11201-728-999	4737

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EXAMINER	
MACNEILL, ELIZABETH	
ART UNIT	**PAPER NUMBER**
3767	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/690,987	GRIFFITHS ET AL.	
	Examiner	Art Unit	
	ELIZABETH R. MACNEILL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/16/08*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 16 December 2008 has been entered.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 29-38:

2. Claims 29,31, 33, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forsberg (US 6,807,797) in view of Drudik (US 5,125,892)

Forsberg discloses that "A typical dual-chamber syringe and a process for automated manufacture of prefilled such syringes is disclosed in Neue Verpackung, No.3, 1988, p. 50-52; Drugs Made in Germany, Vol. 30, Pag. 136-140 (1987); Pharm. Ind. 46, Nr. 10 (1984) p. 1045-1048 and Pharm. Ind. 46, Nr. 3 (1984) p. 317-318. The syringe

type ampoule is a dual chamber device with a front bottle type opening for needle attachment, two pistons and an exterior type by-pass for mixing a lyophilized powder in the front chamber with a reconstitution liquid in the rear chamber. The process described includes the main steps of washing and siliconizing the syringe barrels, insertion of multiple barrels in carrier trays, sterilization, introduction of middle piston through barrel rear end, turning the trays upside down, introduction of the powder solution through the front opening, lyophilization to dry powder, closure of front opening while in the lyophilizing chamber, turning of trays, introduction of the reconstitution liquid through barrel rear end, insertion of rear piston, removal of products from trays and final control and packaging." (Col 2).

Forsberg only discloses the loading procedure for use with mixing syringes where the barrel includes an exterior type by-pass, and therefore does not teach that the chamber has no interior structures, or the seal having a flow path formable there through. Drudik teaches a well-known type of mixing syringe assembly having a front solid (S), a rear liquid (L), a seal (14) having a movable sealing plug (36) operative to move from a sealing position to a by-pass area (Fig 12) to open a flow path (23) there through (Fig 2) and a barrel (1) having no interior structures and a second seal (19). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the seal and barrel structure of Drudik with the loading method of Forsberg in order to provide a syringe which is loaded without mixing of the two compartments and which has an extended shelf life (Col 3 line 23).

3. Claims 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forsberg and Szapiro in view of Odell et al (US 6,263,641).

Forsberg teaches the structural limitations of the syringe being formed as shown above, but does not teach the steps of placing the syringe in an aseptic or low-particulate environment. Odell et al teaches a method of making and assembling medical containers involving using sterile environments (for Figures 1-4) and placing the syringes in a low-particulate environment (when filling the dry component, Col 13 lines 33-50), then packaging the syringes in sterile packaging (an aseptic environment).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of assembly of Odell with the device of Forsberg in order to provide a pre-filled syringe which is safe to use and contains uncontaminated medicament.

4. Claims 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forsberg/ Szapiro /Odell in view of Geprags (US 4,781,701).

Forsberg/ Szapiro and Odell do not discuss the structure of the front seal used with their syringe cartridges. Geprags discloses a front syringe barrel seal with a tapered flow path (at 17).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of assembly of Forsberg/ Szapiro /Odell with the seal of Geprags in order to provide a secure seal of the front end of the syringe (Abstract).

5. Claims 32, 34, 35, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forsberg/ Szapiro /Odell in further view of Tanaka et al (US 5,716,339).

Forsberg/ Szapiro and Odell do not disclose filling the rear compartment with a wet medicament before filling the front chamber. Tanaka teaches filling the rear chamber first (Fig 2A) and then filling the front chamber with a dry medication (Fib 2B). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of Tanaka when filling the syringes in order to prevent mixing of the ingredients.

Claims 39-44:

6. Claims 39, 41, 43, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forsberg (US 6,807,797) in view of Drudik (US 5,125,892) in view of Odell et al (US 6,263,641) and further in view of Shields (US 3,807,119)

Forsberg discloses that "A typical dual-chamber syringe and a process for automated manufacture of prefilled such syringes is disclosed in Neue Verpackung, No.3, 1988, p. 50-52; Drugs Made in Germany, Vol. 30, Pag. 136-140 (1987); Pharm. Ind. 46, Nr. 10 (1984) p. 1045-1048 and Pharm. Ind. 46, Nr. 3 (1984) p. 317-318. The syringe type ampoule is a dual chamber device with a front bottle type opening for needle attachment, two pistons and an exterior type by-pass for mixing a lyophilized powder in the front chamber with a reconstitution liquid in the rear chamber. The process described includes the main steps of washing and siliconizing the syringe barrels, insertion of multiple barrels in carrier trays, sterilization, introduction of middle piston

through barrel rear end, turning the trays upside down, introduction of the powder solution through the front opening, lyophilization to dry powder, closure of front opening while in the lyophilizing chamber, turning of trays, introduction of the reconstitution liquid through barrel rear end, insertion of rear piston, removal of products from trays and final control and packaging." (Col 2).

Forsberg only discloses the loading procedure for use with mixing syringes where the barrel includes an exterior type by-pass, and therefore does not teach that the chamber has no interior structures, or the seal having a flow path formable there through. Drudik teaches a well-known type of mixing syringe assembly having a front solid (S), a rear liquid (L), a seal (14) having a movable sealing plug (36) operative to move from a sealing position to a by-pass area (Fig 12) to open a flow path (23) there through (Fig 2) and a barrel (1) having no interior structures. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the seal and barrel structure of Drudik with the loading method of Forsberg in order to provide a syringe which is loaded without mixing of the two compartments and which has an extended shelf life (Col 3 line 23).

Forsberg teaches the structural limitations of the syringe being formed as shown above, but does not teach the steps of placing the syringe in an aseptic or low-particulate environment. Odell et al teaches a method of making and assembling medical containers involving using sterile environments (for Figures 1-4) and placing the

syringes in a low-particulate environment (when filling the dry component, Col 13 lines 33-50), then packaging the syringes in sterile packaging (an aseptic environment).
It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of assembly of Odell with the device of Forsberg in order to provide a pre-filled syringe which is safe to use and contains uncontaminated medicament.

Forsberg and Drudik do not teach the open-mouth configuration of the front end of the syringe. Drudik shows that the front end of his syringe is flat and then extends to a tapered nozzle (5, Fig 1). Shields teaches a syringe with flat front end and open neck (7) through which dry medicament is inserted (Fig 1I-1K). It would have been obvious to one of ordinary skill in the art to use an open neck at the front end of the syringe of Drudik as taught by Shields to facilitate loading of dry powder through the front of the syringe as taught by the method of Forsberg.

7. Claims 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forsberg/ Drudik /Odell/ Shields in view of Geprags (US 4,781,701).
Forsberg/ Drudik /Odell/ Shields do not discuss the structure of the front seal used with their syringe cartridges. Geprags discloses a front syringe barrel seal with a tapered flow path (at 17).
It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of assembly of Forsberg/ Drudik /Odell/ Shields with the

seal of Geprags in order to provide a secure seal of the front end of the syringe (Abstract).

8. Claims 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forsberg/ Drudik /Odell/ Shields in further view of Tanaka et al (US 5,716,339). Forsberg/ Drudik /Odell/ Shields do not disclose filling the rear compartment with a wet medicament before filling the front chamber. Tanaka teaches filling the rear chamber first (Fig 2A) and then filling the front chamber with a dry medication (Fib 2B). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of Tanaka when filling the syringes in order to prevent mixing of the ingredients.

Claims 45-50:

9. Claims 45,47,49,50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forsberg (US 6,807,797) in view of Drudik (US 5,125,892) and in view of Shields (US 3,807,119).

Forsberg discloses that "A typical dual-chamber syringe and a process for automated manufacture of prefilled such syringes is disclosed in Neue Verpackung, No.3, 1988, p. 50-52; Drugs Made in Germany, Vol. 30, Pag. 136-140 (1987); Pharm. Ind. 46, Nr. 10 (1984) p. 1045-1048 and Pharm. Ind. 46, Nr. 3 (1984) p. 317-318. The syringe type ampoule is a dual chamber device with a front bottle type opening for needle attachment, two pistons and an exterior type by-pass for mixing a lyophilized powder in the front chamber with a reconstitution liquid in the rear chamber. The process described includes the main steps of washing and siliconizing the syringe barrels,

insertion of multiple barrels in carrier trays, sterilization, introduction of middle piston through barrel rear end, turning the trays upside down, introduction of the powder solution through the front opening, lyophilization to dry powder, closure of front opening while in the lyophilizing chamber, turning of trays, introduction of the reconstitution liquid through barrel rear end, insertion of rear piston, removal of products from trays and final control and packaging." (Col 2).

Forsberg only discloses the loading procedure for use with mixing syringes where the barrel includes an exterior type by-pass, and therefore does not teach that the chamber has no interior structures, or the seal having a flow path formable there through.

Drudik teaches a well-known type of mixing syringe assembly having a front solid (S), a rear liquid (L), a seal (14) having a movable sealing plug (36) operative to move from a sealing position to a by-pass area (Fig 12) to open a flow path (23) there through (Fig 2) and a barrel (1) having no interior structures. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the seal and barrel structure of Drudik with the loading method of Forsberg in order to provide a syringe which is loaded without mixing of the two compartments and which has an extended shelf life (Col 3 line 23).

Forsberg and Drudik do not teach the open-mouth configuration of the front end of the syringe. Drudik shows that the front end of his syringe is flat and then extends to a tapered nozzle (5, Fig 1). Shields teaches a syringe with flat front end and open neck (7) through which dry medicament is inserted (Fig 1I-1K). It would have been obvious to one of ordinary skill in the art to use an open neck at the front end of the syringe of

Drudik as taught by Shields to facilitate loading of dry powder through the front of the syringe as taught by the method of Forsberg.

10. Claims 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forsberg/Drudik/Shields in view of Geprags (US 4,781,701).

Forsberg/Drudik/Shields do not discuss the structure of the front seal used with their syringe cartridges. Geprags discloses a front syringe barrel seal with a tapered flow path (at 17).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of assembly of Forsberg/Drudik/Shields with the seal of Geprags in order to provide a secure seal of the front end of the syringe (Abstract).

11. Claims 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forsberg/Drudik/Shields in further view of Tanaka et al (US 5,716,339).

Forsberg/Drudik/Shields do not disclose filling the rear compartment with a wet medicament before filling the front chamber. Tanaka teaches filling the rear chamber first (Fig 2A) and then filling the front chamber with a dry medication (Fib 2B). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of Tanaka when filling the syringes in order to prevent mixing of the ingredients.

Response to Arguments

1. Applicant's arguments with respect to claims 29-50 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner MacNeill whose telephone number is (571)272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth R MacNeill/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767